

REMARKS

1. Introduction

The Office Action dated April 15, 2008, has been received and the cited references have been considered. Claims 1-12 have been examined and claims 13-28 have been withdrawn. In this response, claims 1, 2, 6, 9, and 11 have been amended and claims 29-34 have been added. No new matter has been added. Entry of the amendments to claims 1, 2, 6, 9, and 11, and the addition of claims 29-34 is respectfully requested. Reconsideration of the outstanding rejection and allowance of the application are respectfully requested based on the following remarks.

2. The Obviousness Rejections of Claims 1-12

On page 2 of the Office Action, claims 1-3 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,037,602 to Dabiri et al. ("Dabiri") in view of U.S. Patent No. 6,445,146 to Bergstrom et al. ("Bergstrom") and in further view of U.S. Patent No. 4,943,781 to Wilson et al. ("Wilson"). On page 3 of the Office Action, claims 1-2 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Wilson and furthermore in view of Applicant's own disclosure. On page 3 of the Office Action, claims 1 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Wilson and furthermore in view of U.S. Patent No. 6,392,246 to Wiberg et al. ("Wiberg"). On page 3 of the Office Action, claims 1 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Wilson and furthermore in view of U.S. Patent No. 6,437,344 to Strawson ("Strawson"). On page 3 of the Office Action, claims 1, 2, 6, and 9-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Wilson and furthermore in view of U.S. Patent No. 4,428,908 to Ashley et al. ("Ashley"), U.S.

Patent No. 5,927,351 to Zhu et al. ("Zhu"), and U.S. Patent No. 3,411,002 to Armel ("Armel").

On page 3 of the Office Action, claims 1-3 and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dabiri in view of Bergstrom and in further view of Wilson and furthermore in view of Wiberg and Zhu. These rejections are respectfully traversed.

Under 35 U.S.C. § 103, the U.S. Patent and Trademark Office bears the burden of establishing a *prima facie* case of obviousness. In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). There are four separate factual inquiries to consider in making an obviousness determination: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3) the differences between the claimed invention and the prior art; and (4) the existence of any objective evidence, or "secondary considerations," of non-obviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); see also KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). An "expansive and flexible approach" should be applied when determining obviousness based on a combination of prior art references. KSR, 127 S. Ct. at 1739. However, a claimed invention combining multiple known elements is not rendered obvious simply because each element was known independently in the prior art. Id. at 1741. Rather, there must still be some "reason that would have prompted" a person of ordinary skill in the art to combine the elements in the specific way that he or she did. Id.; In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1380 (Fed. Cir. 2007). Also, modification of a prior art reference may be obvious only if there exists a reason that would have prompted a person of ordinary skill to make the change. KSR, 127 S. Ct. at 1740-41.

The Office Action asserts that Dabiri discloses a transportable radioisotope production facility, particularly a radio frequency quadrupole (RFQ) linear accelerator that produces

radioisotopes having application to Positron Emission Tomography (PET). The Office Action admits, and Applicant agrees, that Dabiri fails to disclose, or even suggest, a cyclotron. However, the Office Action asserts that Bergstrom teaches a compact cyclotron suitable for installation in a PET isotope production facility. Also, the Office Action asserts that Wilson teaches a "highly transportable" cyclotron with reduced size and weight due to lack of iron yoke for the magnet. Therefore, the Office Action concludes that a person of ordinary skill in the art would modify the teaching of Dabiri with the cyclotron of Bergstrom and Wilson because the space limitations presented by an ordinary cyclotron in a transportable facility could be overcome by a more compact cyclotron. Applicant respectfully disagrees. Applicant respectfully submits that the Office Action fails to establish *prima facie* case of obviousness. Specifically, Applicant submits that Dabiri teaches away from replacing the radio frequency quadrupole (RFQ) linear accelerator in a transportable radioisotope product facility of Dabiri with the cyclotron of Bergstrom and Wilson for several reasons.

First, Applicant respectfully submits that Dabiri discloses that an amount of shielding for a radio frequency quadrupole (RFQ) linear accelerator is less than an amount of shielding for a cyclotron. In particular, Dabiri discloses that the radio frequency quadrupole (RFQ) linear accelerator is based on a neutron-poor reaction which results from a $^3\text{He}++$ bombardment of the target material and thus, significantly reduces the amount of shielding that is required around the target chamber." *See, e.g.,* column 3, lines 27-30. Specifically, Dabiri discloses that "due to the neutron-poor nature of the $^3\text{He}++$ beam and resulting reactions, no shielding around the accelerator and little shielding around the target chamber is required relative to existing cyclotron-based PET systems." *See, e.g.,* column 4, lines 49-53. As illustrated in Figures 2 and

10 of Dabiri, "no shielding is required around the radio frequency quadruple (RFQ) 34, thereby significantly reducing the quantity of shielding required." *See, e.g.*, column 6, lines 55-57. Particularly, Dabiri discloses that "unlike most reactions for proton and deuteron-based systems which involve neutrons in the final state, most of the ^3He -based reactions involve a charged particle in the final state. Such particles can be easily shielded by sheets of aluminum or the target casting itself. *See, e.g.*, column 7, lines 21-26. Therefore, Dabiri discloses that the reduced shielding requirements, coupled with the small radio frequency quadruple (RFQ) linear accelerator, makes possible a PET system to efficiently generate the needed radionuclides for PET applications. *See, e.g.*, column 3, lines 36-41. Thus, Applicant respectfully submits that the radio frequency quadruple (RFQ) linear accelerator of Dabiri requires less shielding than the cyclotron of Bergstrom and Wilson and therefore one having ordinary skill in the art would not have replaced the radio frequency quadruple (RFQ) linear accelerator with a cyclotron.

Second, Applicant respectfully submits that Dabiri discloses that an amount of power consumed for a radio frequency quadruple (RFQ) linear accelerator is less than an amount of power consumed for a cyclotron. In particular, Dabiri discloses that "advantageously, the radio frequency quadruple (RFQ) linear accelerator is a small, light-weight device and requires significantly less operating power than does the cyclotron." *See, e.g.*, column 3, lines 16-18. Specifically, Dabiri discloses that the radio frequency quadruple (RFQ) linear accelerator system "operates on roughly 1/5 of the operating power required by the cyclotron-based PET system." *See, e.g.*, column 4, lines 18-20. Therefore, Dabiri discloses that "the reduced shielding requirements, coupled with the small RFQ accelerator and the relatively low power requirements therefore, as well as the efficient use of the target material, makes possible a PET system" to

efficiently generate the needed radionuclides for PET applications. *See, e.g.,* column 3, lines 36-41. Therefore, Applicant respectfully submits that one having ordinary skill in the art would not replace the low power consumption radio frequency quadrupole (RFQ) linear accelerator of Dabiri with the high power consumption cyclotron of Bergstrom and Wilson.

Third, Applicant respectfully submits that Dabiri discloses that an amount of neutron produced by a radio frequency quadrupole (RFQ) linear accelerator is less than an amount of neutrons produced by a cyclotron. In particular, Dabiri discloses that the ^3He -based reactions "significantly reduce the neutron production in the targets relative to that in the protons and deuteron targets." *See, e.g.,* column 7, lines 27-29. Moreover, Dabiri discloses that the "low neutron production significantly reduces the shielding requirements" of the radio frequency quadrupole (RFQ) linear accelerator system. *See, e.g.,* column 7, lines 36-38. Therefore, Applicant respectfully submits that one having ordinary skill in the art would not replace the low level neutron producing radio frequency quadrupole (RFQ) linear accelerator of Dabiri with the high level neutron producing cyclotron of Bergstrom and Wilson.

Furthermore, Applicant respectfully submits that Dabiri discloses that extraction is not required for a radio frequency quadrupole (RFQ) linear accelerator as is required for a cyclotron. Particularly, Dabiri discloses that "no extraction system is required to extract the $^3\text{He}^{++}$ beam from the radio frequency quadrupole (RFQ) linear accelerator as is required to extract a proton/deuteron beam from a cyclotron." *See, e.g.,* column 4, lines 40-43. Also, Dabiri discloses that beam activation problems associated with cyclotron are eliminated with the radio frequency quadrupole (RFQ) linear accelerator system. Specifically, Dabiri discloses that the radio frequency quadrupole (RFQ)-based accelerator system has no beam activation problems as

are common with proton/deuteron beam systems. *See, e.g.*, column 6, lines 50-52. In addition, Dabiri discloses that the $^3\text{He}++$ target reactions have the property that fewer neutrons are produced per isotope nucleus than with low energy proton or deuteron based systems and thus results in the elimination of the radiation shielding for the accelerator. *See, e.g.*, column 16, line 67 to column 18, line 3. For all of the foregoing reasons, Applicant respectfully submits that Dabiri teaches away from replacing the radio frequency quadrupole (RFQ) linear accelerator with the cyclotron of Bergstrom and Wilson. Therefore, Applicant respectfully submits that the Office Action failed to establish a *prima facie* case of obviousness because the claim rejection is improperly based on hindsight, as Dabiri in fact strongly teaches away from the use of a cyclotron for many reasons described above.

Furthermore, even the cyclotron disclosed by Bergstrom and the cyclotron disclosed by Wilson are distinct and teach away from each other. Specifically, Wilson discloses a cyclotron including an “axial magnetic field provided by *yokeless* means in the form of a superconducting magnet 29 having a set of superconducting magnet coils 21 through to 24 which are housed in a cryostat 25.” *See* Wilson column 2, lines 53-56; *See also* Wilson at col. 1, lines 57-59 (“The present invention provides a design of cyclotron using a superconducting magnet *which has no iron yoke.*”). In contrast, Bergstrom discloses a cyclotron including an “electromagnetic field created between the magnet poles 1 and 2 by means of coils arranged on a yoke.” *See* Bergstrom col. 4, lines 14-19. Therefore, Wilson teaches away from using a yoke for generating a magnetic field as disclosed by Bergstrom.

In short, Applicant respectfully submits that the Office Action improperly relies to a large degree on hindsight to piece together the limitations recited in claim 1. Therefore, the Office

Action fails to establish a *prima facie* case of obviousness to combine Dabiri, Bergstrom and Wilson. Accordingly, reconsideration and withdrawal of the rejection of claim 1 is respectfully requested. The dependent claims are allowable for at least the same reasons that claim 1 is allowable.

Regarding claims 2-12, it is respectfully submitted that the aforementioned obviousness rejection of claims 2-12 has become moot in view of the deficiencies of the primary references (i.e., Dabiri, Bergstrom, and Wilson) as discussed above with respect to independent claim 1. That is, claims 2-12 are dependent upon independent claim 1 and thus inherently incorporate all of the limitations of independent claim 1. Also, the secondary references (i.e., AAPA, Wiberg, Strawson, Ashley, Zhu, and Armel) fail to disclose, or even suggest, the deficiencies of the primary references as discussed above with respect to independent claim 1. Indeed, the Examiner does not even assert such. Thus, the combination of the secondary references with the primary references also fails to disclose, or even suggest, the deficiencies of the primary references as discussed above with respect to independent claim 1. Accordingly, claims 2-12 are allowable over the combination of the secondary references with the primary references at least by virtue of their dependency on independent claim 1. Moreover, claims 2-12 recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination.

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-12 be withdrawn.

3. New Claims 29-34

To further define the protection to which Applicant is entitled, new claims 29-34 are submitted. The new claims are patentable over the cited references because the new claims recite combinations of features that are not disclosed or suggested by the cited references. For example, claim 30 recites “equipping the manufacturing facility with a synthesis unit and a packaging area, wherein the packaging area allows labeling of containers containing the radiopharmaceutical and entering of records of production and delivery of the pharmaceutical,” and “the manufacturing facility is designed to satisfy substantially all legal and regulatory requirements of the jurisdiction in which the site is located,” which is not disclosed or suggested by the cited references. In addition, claim 33 recites “equipping the manufacturing facility with radiopharmaceutical packaging equipment prior to transporting the manufacturing facility to the site,” which is not disclosed or suggested by the cited references. Moreover, claim 34 recites “equipping the manufacturing facility with a clean room for dispensing the radiopharmaceutical into one or more containers prior to transporting the manufacturing facility to the site,” which is not disclosed or suggested by the cited references.

In view of the foregoing, the allowance of newly added claims 29-34 is respectfully requested.

4. Conclusion

In view of the above remarks, Applicant respectfully submits that the present application is in condition for allowance, and notice to that effect is respectfully solicited. If there are any questions regarding this Amendment or the application in general, the Examiner is encouraged to contact the undersigned to expedite prosecution.

Submitted herewith is a petition for a 1-month extension of time including an authorization to charge the required petition fee. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

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Dated: August 7, 2008

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